36. (Amended) A composition of matter comprising

a covalent conjugate of a bioactive agent and a polysaccharide that is an LPS core moiety comprising

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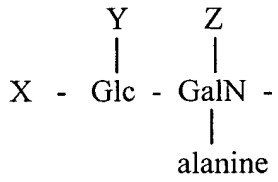

wherein X is selected from the group consisting of glucose, glucose-rhamnose and H; Y is selected from the group consisting of rhamnose and H; and Z is selected from the group consisting of glucose and H.

REMARKS

Applicant has amended claims 14, 26, 32, and 36. Claims 14-43 are pending. No new matter has been added.

Claims Objections

Claims 14 and 32 have been objected to because of typographical errors. Applicant has amended the claims. It is believed that the amendment is sufficient to overcome the objection.

Rejection of Claims 14-43 Under 35 U.S.C. §112, Second Paragraph

Claims 14-43 have been rejected under 35 U.S. C. §112, second paragraph, as being indefinite for two reasons set forth by the Examiner.

It has been asserted that claims 14-25 are indefinite because of the term "therapeutically effective amount". Applicant has amended claim 14 to remove the limitation of the "therapeutically effective amount". It is Applicant's belief that the 112 issue with respect to this term was satisfied by the addition of the limitation that the amount was for upregulating CFTR expression. In order to expedite prosecution, however, Applicant has amended the claim.

Claims 26-43 have been rejected for the reasons of record and because, according to the Examiner, the claims do not recite the lipid core moiety. Applicant has amended independent

claims 26 and 36 to add the language that was found to be acceptable in claim 14. These claims now recite a LPS core moiety.

Rejection of Claims 26-43 Under 35 U.S.C. §102

Claims 26-43 have been rejected under 35 U.S.C. §102 as being anticipated by Masoud et al. According to the Examiner, Masoud et al. teaches the isolation of LPS "core" of *P. aeruginosa* and that the core contains an alanine. The Examiner indicates that the terms "bioactive agent" and "covalent conjugate" in the claims are interpreted broadly to include the polysaccharide portions of the LPS.

Masoud et al. demonstrates the core structure for LPS obtained from *P. aeruginosa* serotype 06 IATS mutant strain A 28 in figures 8 and 9. Also shown in figure 9 are the core structures previously illustrated by Drewry et al., Rowe and Meadow, and Kropinski et al. The discussion teaches that only partial and tentative structures for the core from LPS of serologically distinct strains of *P. aeruginosa* belonging to serotypes 02, 03, and 05 were proposed. These were the ones shown in figure 9. It further teaches that an accurate chemical structure for this region has not yet been reported.

Claims 26-43 are not anticipated by Masoud et al. because the compositions claimed therein encompass a covalent conjugate of the polysaccharide core with either a non-toxic lipid or a bioactive agent. Masoud et al., does not disclose a covalent conjugate of the described core material with either a non-toxic lipid or a bioactive agent.

Claim 26 recites a covalent conjugate of a non-toxic lipid and a polysaccharide having the core presented in the claim. Masoud et al., does not disclose a covalent conjugate of the described core material with a non-toxic lipid. No matter how broadly the language "non-toxic lipid" is read, the Masoud reference does not describe a core material conjugated to a non-toxic lipid. Thus, it is not possible for Masoud et al., to anticipate claim 26 and the claims dependent thereon.

Claim 36 recites a covalent conjugate of a bioactive agent and a polysaccharide having the core presented in the claim. Bioactive agents are known in the art. Additionally, as set forth in the specification on page 13, a bioactive agent includes diagnostic agents and molecules effecting the metabolism of a cell expressing a CFTR, including peptides, nucleic acids, and other natural and synthetic drug molecules. No matter how broadly the term "bioactive agent" is

defined, the Masoud et al. reference does not disclose a core structure conjugated to a bioactive agent. Thus, it is not possible for Masoud et al., to anticipate claim 36 and the claims dependent thereon.

New Rejection of Claims 14-25 Under 35 U.S.C. §112, First Paragraph

Claims 14- 25 have been rejected because according to the Examiner because "while being enabled for therapeutic amount for clearing pseudomonas infection, does not reasonably provide enablement for all infections or diseases." Applicant has amended the claims to remove the language related to "therapeutic amount". It is believed that this amendment is sufficient to overcome the rejection.

Summary of Claims

It is stated that no claims are free of the prior art. However, only claims 26-43 have been rejected in view of prior art. Thus, claims 14-25 must be free of prior art.

Summary

It is believed that each of the pending claims is now in condition for allowance. If the Examiner has any questions, he is encouraged to contact Applicant's representative at the number listed below.

Respectfully submitted,

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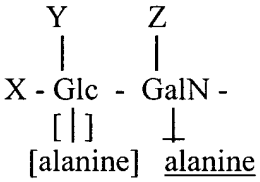
Docket No. B00801.70155.US
Date: April 25, 2003
X05/19/03

MARKED-UP CLAIMS

14. (Twice Amended) A pharmaceutical preparation comprising

[a therapeutically effective amount of] a CFTR expression regulator [for upregulating CFTR expression], wherein the CFTR expression regulator is a polysaccharide that is an LPS core moiety comprising



wherein X is selected from the group consisting of glucose, glucose-rhamnose and H;

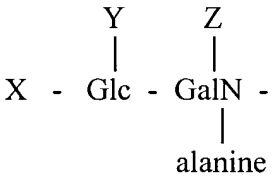
wherein Y is selected from the group consisting of rhamnose and H; and

wherein Z is selected from the group consisting of glucose and H; and

a pharmaceutically acceptable carrier.

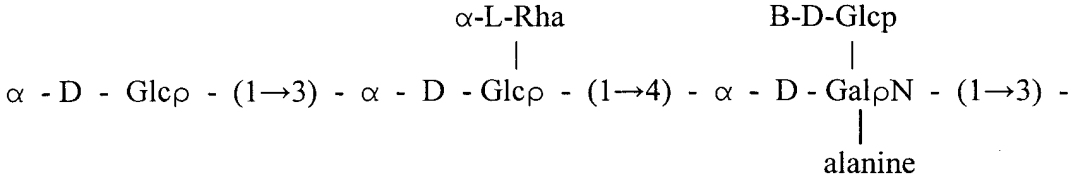
26. (Twice Amended) A composition of matter comprising

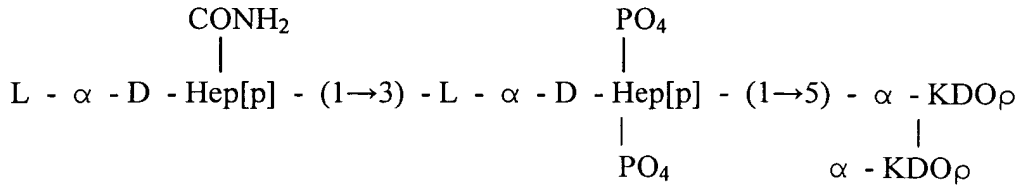
a covalent conjugate of a non-toxic lipid and a polysaccharide that is an LPS core moiety comprising



wherein X is selected from the group consisting of glucose, glucose-rhamnose and H; Y is selected from the group consisting of rhamnose and H; and Z is selected from the group consisting of glucose and H.

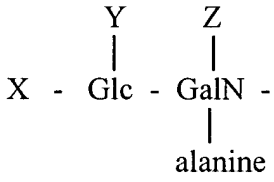
32. (Amended) The composition of matter of claim 26 wherein the polysaccharide comprises





36. (Amended) A composition of matter comprising

a covalent conjugate of a bioactive agent and a polysaccharide that is an LPS core moiety comprising



wherein X is selected from the group consisting of glucose, glucose-rhamnose and H; Y is selected from the group consisting of rhamnose and H; and Z is selected from the group consisting of glucose and H.